

*Ad
correl*
~~restriction~~ fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

49. (New) A maize plant, or parts thereof, produced by the method of claim 47.

REMARKS

Applicant thanks the Examiner for the thorough review of the application.

Applicant investigated the term "gluphosinate" and has been assured that is correctly set forth.

The Examiner objected the disclosure because it contained an embedded hyperlink and/or other form of browser-executable code. Applicant complies with Examiner's request to delete the embedded hyperlink on pages 21 and 24.

Claims 1-2, 18, and 40 were objected to for the inclusion of a blank line where the ATCC accession number should appear. In response, Applicant has amended claims 1-2, 18, and 40 by including the Accession No. "PTA-2886" corresponding to the inbred maize line NP2171.

Claims 1-2, 6-18, 20-22, 26-28, 32-34, 37-38 and 40-41 have been amended in accordance with Examiner's suggestions in order to overcome the rejections set forth by the Examiner.

Claims 20, 26, and 32 are amended by deleting reference to parents being "different." Applicant submits that is well known to plant breeders and others skilled in the art what type of inbred parents are required to cross to obtain F1 hybrid seed. Thus, in view of the amendments to claims 20, 26, and 32, and in view of the substantial knowledge of those persons skilled in the breeding arts, these claims are no longer indefinite, and Applicant respectfully requests the rejection be withdrawn.

The preambles of claims 37 and 40 are amended to clarify the purpose of the claimed method, i.e., to produce inbred line NP2171.

Claim 42 is rejected for indefiniteness. The Examiner states that what is being retained in the derived plant is unclear, and that the recited traits lack comparative basis. Applicant respectfully submits that all the claimed traits being retained are explicitly recited in the claim, and are definite and clearly described in the specification. All the traits listed in claim 42 are quantitatively defined and described in Table 1. In addition, the claimed traits are quantitatively compared with a reference plant A632. Furthermore, any non-NP2171 traits are simply “conventional” features, and are not essential to the operation/function of the claimed invention. See, *Synopsis of Application of Written Description Guidelines*, page 1 of section entitled, *Written Description, Original Claims, Decision* found on the USPTO website.

Furthermore, Applicant respectfully submits that plant breeders have substantial knowledge of the plant traits recited in claim 42. The significance and meaning of these traits are taught in many undergraduate and graduate school programs. Plant breeders are able to differentiate the significance between different expression levels and different combinations of these traits, and can determine the novelty of the particular combinations of traits of inbred maize line NP2171. To those skilled in the art, there is no ambiguity and lack of clarity to the traits recited in claim 42 as defined and compared in Table 1. Applicant also respectfully points out that it is well settled in patent law that “information that is well known in the art need not be described in detail in the specification.” (Section II, subparagraph 2 of the *Guidelines for the Examination of Patent Applications under 35 USC 112*, ¶1.) Thus, taking into account the substantial knowledge of those skilled in the plant breeding arts, Applicant respectfully submits that claim 42 is not indefinite.

Claim 42 also stands rejected under 35 U.S.C. 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention, and that the claimed invention lacks written description under current written description guidelines. Applicant respectfully disagrees.

The first paragraph of 35 U.S.C. 112 requires that the patent specification clearly convey the information that the applicant has invented and is in possession of the subject matter that is claimed. *In re Barker*, 559 F.2d 588 (CCPA 1977). In *Amgen v. Chugai Pharmaceutical*, 957 F.2d 1200, 1206 (Fed. Cir. 1991), the court determined that a claimed compound was adequately described if the specification describes “whatever characteristics sufficiently distinguish it.” Applicant respectfully submits that the subject specification clearly establishes that the Applicant had invented and was in possession of the claimed invention at the time the application was filed. Applicant now responds to each of the Examiner’s grounds for rejecting claim 42 under 35 USC 112. The Examiner makes the following statements on page 4 of the Office Action in support of the first paragraph 112 rejection:

- The claim is drawn to NP2171-derived maize plants of an unknown number of generations which are only known to have one ancestor of a NP2171 plant.
- The specification only discloses a single inbred maize line, NP2171 with specified characteristics.
- The claim does not recite that the plants retain all the morphological and physiological characteristics of the NP-2073 maize plants.
- There are no relevant identifying characteristics which would allow one skilled in the art to predictably determine what will be the physiological and morphological characteristics of a NP2171-derived maize plants.
- The only characteristics disclosed for the plants are the expression of the combination of at least two traits which is described with relative terms that lack comparative basis.

With regard to the first listed statement, claim 42 is not limited by the number of generations between the ancestor plant NP2171 and the plant of claim 42. The fact that there are 1 or 100 generations between the ancestor plant NP2171 and the subject matter of claim 42 does not make the subject matter of claim 42 not adequately described. The Examiner appears to be mixing the enablement requirement with the written description requirement. With regard to enablement, breeding and selecting for particular traits in succeeding generations is well know by those skilled in the plant breeding art. The fact that significant routine screening is required doesn’t demonstrate that the subject claim is not enabled. “The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine.” *In re Wands* 8 U.S.P.Q.2d 1400

(Fed. Cir. 1988). Novelty of claim 42 resides in the maize inbred line NP2171 and two or more of its non-obvious traits derived therefrom. The traits listed in claim 42 are fully described as Applicant argues above on page 9, lines 3-21; and developing progeny 1 or 100 generations downstream from NP2171 is within the scope of a typical skilled person in the maize breeding art.

The Examiner also states that the specification only discloses a single inbred maize line, NP2171 with specified characteristics, and that as a result claim 42 is not adequately described. Again, the Applicant respectfully disagrees with the Examiner's analysis. Claim 1 and 2 claim seed and plants of maize inbred line NP2171. Claim 42 claims a "NP2171-derived maize plant" (Emphasize added). Any inbred maize line that is not a seed or plant of NP2171 falls outside the genus of claims 1, 2 and the subject matter (recited traits) of claim 42. There is simply no requirement under 35 U.S.C. 112 that Applicant describe plants that fall outside of the genus and subject matter claimed.

The Examiner further states that the claim does not recite that the plants retain all the morphological and physiological characteristics of the NP2171 maize plant. Applicant fails to understand how this statement relates to the written description requirement of 35 U.S.C. 112. Claim 42 is not directed to "all of the morphological physiological characteristics of the NP2171 maize plant." Claim 42 recites a species of NP2171, i.e., a "NP2171-derived plant, or parts thereof" (emphasize added). Claim 42 also requires that the claimed NP2171-derived plant, or parts thereof, be capable of expressing at least two traits. The traits aren't just any traits; they are traits that are derived from the maize inbred plant NP2171 and that are explicitly listed in a Markush grouping. Furthermore, the traits listed in claim 42 are described and quantified in the subject application on pages 12-15, where they are compared in detail to the corresponding traits of inbred maize plant A632. Thus, based on the substantial description of these traits in the specification, Applicant respectfully submits that the subject matter of claim 42 is adequately described.

In further support, Applicant points out that one skilled in the art understands what is being described by the list of traits set forth on pages 12-19, and in claim 42. In fact, people skilled in the maize plant breeding art have a working and detailed knowledge of each one of the listed traits, and understand the quantitative and comparative data set for on pages 12-15 of the specification. The

current written description guidelines recognize the inverse relationship between the level of skill in the art and the disclosure necessary to satisfy the written description requirement: “Information that is well known in the art need not be described in detail in the specification.” (Section II, subparagraph 2 of the *Guidelines for the Examination of Patent Applications under 35 USC 112*, ¶1.) Applicant again respectfully submits that the specification adequately describes the subject matter of claim 42.

The Examiner also states that there are no relevant identifying characteristics which would allow one skilled in the art to predictably determine what will be the physiological and morphological characteristics of a NP2171-derived maize plants. Applicant refers the Examiner to Applicant’s remarks immediately above, and again points out that claim 42 recites two requirements, first that NP2171 be an ancestor of the plant, and second that the claimed plant expresses a combination of at least two NP2171 traits selected from a Markush grouping. Novelty doesn’t lie in, and claim 42 does not claim, any non-NP2171 traits that the plant may contain. Therefore, Applicant respectfully submits that the patent specification clearly conveys the information that the applicant has invented and is in possession of the subject matter that is claimed.

The Examiner further states the only characteristics disclosed for the plants are the expression of the combination of at least two traits which is described with relative terms that lack comparative basis. In response, Applicant again states that the traits are described in detail on pages 12-19 of the specification and in relationship to the reference maize inbred line A632. As also stated above, people skilled in the maize plant breeding art have substantial and detailed knowledge of each one of the listed traits, and therefore, according to case law, these traits need not be described in detail in the specification. Thus, Applicant respectfully submits that the traits required in claim 42 are described in a concrete manner in the subject specification such that a person skilled in the art would understand that the Applicant had possession of the invention as of the filing date of the invention.

The Examiner also cites *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1298 (Fed. Cir. 1997) for the proposition that the written restriction requirement is not met when the

applicant names “a type of material generally known to exist, in the absence of knowledge as to what that material consists of...” Applicant refers the Examiner to Applicant’s above remarks, and submits that the description on page 12-19 provides adequate description of the traits claimed in claim 42. There is simply no absence of knowledge of those skilled in the art as to “what the [claimed] material consists of.”

Furthermore, Applicant respectfully submits that there is no lack of ability to “visualize or recognize the identity of members of the genus.” In the *Eli Lilly* case, the claimed subject matter was the genera of vertebrate and mammal cDNA encoding for a protein. The cDNA was only described by naming the claimed subject matter, i.e., cDNA. The Applicant in that case had not sequenced the cDNA, nor had Applicant described any of the structural characteristics of the cDNA. As a huge number of cDNA’s can encode for a protein (insulin), the claims were invalidated by the Federal Circuit because they concluded that in that case the inventors did not have possession of the invention, the cDNA, at the time the application was filed. Applicant first points out that *Eli Lilly* related to a claim covering cDNA, not to a claim covering a plant containing particular traits. In the subject application, the plant traits are described, quantified, and then compared to a reference plant variety. There is simply no comparison between claimed plant variety traits as described in detail on pages 12-15 of the subject specification, and failing to provide a description of specific claimed cDNA as in *Eli Lilly*. Applicant respectfully submits that the subject matter of *Ely Lilly* is not apposite to the subject matter of claim 42 of the present application.

Applicant further submits that in significant contrast to having not a single cDNA species described as in the *Eli Lilly* case, the present application describes each claimed species in detail. Each species of claim 42 encompasses a NP2171-derived maize plant that expresses a combination of at least two NP2171 traits selected from a Markush grouping. The fact that the plant may contain non-NP2171 traits is irrelevant to the claimed subject matter. The non-NP2171 are simply “conventional” features, and not essential to the operation/function of the claimed invention. See, *Synopsis of Application of Written Description Guidelines*, page 1 of section entitled, *Written Description, Original Claims, Decision* found on the USPTO website. On page 3 of the same section of the *Synopsis*, it is stated that if there is a representative number of species implicitly disclosed, the written description requirement is met. No other description is required under 35

USC 112. Applicant respectfully requests, in view of the above remarks, that the Examiner withdraw the 35 U.S.C. 112 first paragraph rejection.

The Examiner rejects claim 42 under 35 U.S.C. 102b as being unpatentable over Mies et al (US Pat. No. 5,792,906). “When the defense of lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims...” C.R. Bard, Inc. v. M3 Systems, Inc. 157 F.3d 1340, 48 USPQ2d 1225 (Fed. Cir. 1998) *rehearing denied and suggestion for rehearing in banc declined*, 161 F.3d 1380 (Fed. Cir. 1998). The ‘906 patent does not describe all of the elements of the subject matter of claim 42, and thus must fail as 102(b) art. For example, the ‘906 patent describes an inbred corn line that has a relative maturity rating of 115-125 days, whereas the relative maturity rating of the claimed plant NP2171 is 85-105 days. Thus, on this element alone, claim 42 is not anticipated by the ‘906 patent. On this basis, Applicant respectfully requests that the Examiner withdraw the 102(b) rejection.

The Examiner also rejects claims 1-42 under 35 U.S.C. 103(a) as being unpatentable over Mies et al. (U.S. Patent No. 5,792,906). Applicant respectfully submits that the Examiner has not established a prima facie case of obviousness. A prima facie case of obviousness is met when: “First, there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success, Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” MPEP 706.02(j)

Applicant again submits that the ‘906 patent does not teach or suggest a relative maturity of 85-105 days. Thus, on this point alone, Examiner has failed to establish a prima facie case of obviousness. There is no teaching in the ‘906 patent on how one skilled in the art would produce a maize plant having 85-105 days relative maturity while retaining all other traits listed and described in the subject application.

With regard to the other traits listed in claim 42, they are all quantitatively defined in Table 1 that starts on page 12. Table 1 also contains data that quantitatively compares the claimed traits of NP2171 to a reference inbred line identified as A619. The differences between the claimed inbred line NP2171 and the inbred line NP2034 of the '906 patent are readily apparent. For example:

- the inbred line NP2171 has a kernel length of 10.2cm, whereas NP2034 of the '906 patent has a kernel length of 7.5 cm;
- the inbred line NP2171 has a number of ears per stalk at 1.5, whereas NP2034 has 1.4; and
- the inbred line NP2171 has a tassel length of 35.8 cm, whereas NP2034 has a tassel length of 43.4 cm.

These and all the other traits described in Table 1, and their quantitative and comparative data, would be understood by those persons skilled in the art to be significantly different from the CM105, and not obvious at all.


Finally, it is well known that although one could try to develop the NP2171 inbred line of the invention it would be impossible (without using NP2171 itself), due to genetic variation amongst different breeding partners and the recombination events that occur during breeding, to develop a NP2171-like inbred line or one that is substantially similar. Thus, the second element that the Examiner must establish cannot be established, i.e., a reasonable expectation of success. In view of these remarks, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-42 under 35 U.S.C. 103(a).

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made."

In view of the above amendments and remarks, it is submitted that the application is ready for allowance. Early notice to this effect is solicited. If any additional information is needed, the Examiner is invited to call the undersigned attorney at (919) 541-8614.

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Respectfully submitted,

 6/26/02

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Version With Markings To Show Changes Made

In the specification:

The last paragraph beginning on page 20 and continuing on page 21 has been amended as follows:

The laboratory-based techniques described above, in particular RFLP and SSR, are routinely used in such backcrosses to identify the progenies having the highest degree of genetic identity with the recurrent parent. This permits to accelerate the production of inbred maize lines having at least 90%, preferably at least 95%, more preferably at least 99% genetic identity with the recurrent parent, yet more preferably genetically identical to the recurrent parent, and further comprising the trait(s) introgressed from the donor parent. Such determination of genetic identity is based on molecular markers used in the laboratory-based techniques described above. Such molecular markers are for example those known in the art and described in Boppenmaier, et al., "Comparisons among strains of inbreds for RFLPs", Maize Genetics Cooperative Newsletter (1991) 65, pg. 90, or those available from the University of Missouri database and the Brookhaven laboratory database—(see ~~<http://www.agron.missouri.edu>~~). The last backcross generation is then selfed to give pure breeding progeny for the gene(s) being transferred. The resulting plants have essentially all of the morphological and physiological characteristics of inbred maize line NP2171, in addition to the single gene trait(s) transferred to the inbred. Preferably, the resulting plants have all of the morphological and physiological characteristics of inbred maize line NP2171, in addition to the single gene trait(s) transferred to the inbred. The exact backcrossing protocol will depend on the trait being altered to determine an appropriate testing protocol. Although backcrossing methods are simplified when the trait being transferred is a dominant allele, a recessive allele may also be transferred. In this instance it may be necessary to introduce a test of the progeny to determine if the desired trait has been successfully transferred.

The third paragraph on page 24 has been amended as follows:

Specific transgenic events introgressed into maize inbred line NP2171 can be obtained through the list of Petitions of Nonregulated Status Granted by APHIS as of 10-12-2000~~are found at http://www.aphis.usda.gov/bbep/bp/not_reg.html~~. For example, introgressed from glyphosate tolerant event GA21 (9709901p), glyphosate tolerant/Lepidopteran insect resistant event MON 802 (9631701p), Lepidopteran insect resistant event DBT418 (9629101p), male sterile event MS3 (9522801p), Lepidopteran insect resistant event Bt11 (9519501p), phosphinothricin tolerant event B16 (9514501p), Lepidopteran insect resistant event MON 80100 (9509301p), phosphinothricin tolerant events T14, T25 (9435701p), Lepidopteran insect resistant event 176 (9431901p).

The first full paragraph on page 28 has been amended as follows:

Applicants have made a deposit of at least 2500 seeds of Inbred Maize Line NP2171 with the American Type Culture Collection (ATCC), Manassas, Virginia, 20110-2209 U.S.A., ATCC Deposit No: PTA-2886. This deposit of the Inbred Maize Line NP2171 will be maintained in the ATCC depository, which is a public depository, for a period of 30 years, or 5 years after the most recent request, or for the effective life of the patent, whichever is longer, and will be replaced if it becomes nonviable during that period. Additionally, Applicants have satisfied all the requirements of 37 C.F.R. §§1.801-1.809, including providing an indication of the viability of the sample. Applicants impose no restrictions on the availability of the deposited material from the ATCC; however, Applicants have no authority to waive any restrictions imposed by law on the transfer of biological material or its transportation in commerce. Applicants do not waive any infringement of its rights granted under this patent or under the Plant Variety Protection Act (7 USC 2321 et seq.).

In the claims:

The following claims have been amended:

1. (Amended) Seed of maize inbred line NP2171 having been deposited under ATCC Accession No: PTA-2886_____.
2. (Amended) A maize plant, or parts thereof, of inbred line NP2171, seed of said line having been deposited under ATCC Accession No: PTA-2886_____.
6. (Amended) A male sterile maize plant, or parts thereof, otherwise having all the physiological and morphological characteristics of thea plant according to claim 2.
7. (Amended) TheA maize plant, or parts thereof, according to claim 2, further comprising one or more single gene transferred traits.
8. (Amended) TheA maize plant, or parts thereof, according to claim 7, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.
9. (Amended) TheA maize plant according to claim 7, wherein said single gene transferred trait comprises a gene conferring upon said maize plant tolerance to a herbicide.
10. (Amended) TheA maize plant according to claim 9, wherein said herbicide is glyphosate, gluphosinate, a sulfonylurea or an imidazolinone herbicide, a hydroxyphenylpyruvate dioxygenase inhibitor or a protoporphyrinogen oxidase inhibitor.
11. (Amended) TheA maize plant according to claim 7, wherein said single gene transferred trait comprises a gene conferring upon said maize plant insect resistance, disease resistance or virus resistance.
12. (Amended) TheA maize plant according to claim 11, wherein said gene conferring upon said maize plant insect resistance is a *Bacillus thuringiensis* Cry1Ab gene.
13. (Amended) TheA maize plant according to claim 12, further comprising a *bar* gene.

14. (Amended) TheA maize plant according to claim 12, wherein said Cry1Ab gene is introgressed into said maize plant from a maize line comprising a Bt-11 event or a 176 event.

15. (Amended) Seed of thea plant according to claim 7.

16. (Amended) A tissue culture of regenerable cells of thea maize plant according to claim 2, wherein the tissue regenerates plants capable of expressing all the morphological and physiological characteristics of the plants according to claim 2.

17. (Amended) TheA tissue culture according to claim 16, the regenerable cells being selected from the group consisting of embryos, meristems, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks and stalks, or being protoplasts or callus derived therefrom.

18. (Amended) A maize plant regenerated from the tissue culture of claim 16, capable of expressing all the morphological and physiological characteristics of inbred line NP2171, seed of said inbred line having been deposited under ATCC Accession No: PTA-2886_____.

20. (Amended) TheA method according to claim 19, ~~wherein said first parent maize plant is different from said second parent maize plant,~~ wherein said resultant seed is a first generation (F1) hybrid maize seed.

21. (Amended) TheA method according to claim 19, wherein the inbred maize plant of claim 2 is the female parent.

22. (Amended) TheA method according to claim 19, wherein the inbred maize plant of claim 2 is the male parent.

26. (Amended) TheA method according to claim 25, ~~wherein said first parent maize plant is different from said second parent maize plant,~~ wherein said resultant seed is a first generation (F1) hybrid maize seed.

27. (Amended) ~~The~~A method according to claim 25, wherein the inbred maize plant of claim 5 is the female parent.

28. (Amended) ~~The~~A method according to claim ~~25~~7, wherein the inbred maize plant of claim 5 is the male parent.

32. (Amended) ~~The~~A method according to claim 31, ~~wherein said first parent maize plant is different from said second parent maize plant,~~ wherein said resultant seed is a first generation (F1) hybrid maize seed.

33. (Amended) ~~The~~A method according to claim 31, wherein the inbred maize plant of claim 7 is the female parent.

34. (Amended) ~~The~~A method according to claim 31, wherein the inbred maize plant of claim 7 is the male parent.

37. (Amended) A method for producing inbred line NP2171, representative seed of which has been deposited under ATCC Accession No. PTA-2886 comprising:

(a) planting a collection of seed comprising seed of a hybrid, one of whose parents is a plant according to claim 2, or a maize plant having all the physiological and morphological characteristics of a plant according to claim 2, said collection also comprising seed of said inbred line;

(b) growing plants from said collection of seed;

(c) identifying said inbred plants, wherein said inbred plants are identified by their decreased vigor;

(d) selecting said inbred plant; and

(e) controlling pollination in a manner which preserves the homozygosity of said inbred plant.

38. (Amended) ~~The~~A method according to claim 37, wherein said one parent is ~~the~~a plant of inbred maize line NP2171, further comprising a single gene transferred trait.

40. (Amended) A method comprising introgressing a single gene trait into inbred maize line NP2171, seed of said line having been deposited under ATCC Accession No: PTA-2886_____, using one or more markers for marker assisted selection among maize lines to be used in a maize breeding program, the markers being associated with a single gene trait, wherein the resulting maize line is inbred maize line NP2171 further comprising said single gene transferred trait.

41. (Amended) ~~The~~A method according to claim 40, wherein said a single gene trait comprises a Cry1Ab gene.

The following claims have been added:

43. (New) The maize plant, or parts thereof, of claim 5, wherein the plants or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.

44. (New) A method for producing a maize plant that contains in its genetic material one or more transgenes, comprising crossing the maize plant of claim 43 with either a second plant of another maize line, or a non-transformed maize plant of the line NP2171, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.

45. (New) The maize plant, or parts thereof, of claim 8, wherein the plants or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.

46. (New) A method for producing a maize plant that contains in its genetic material one or more transgenes, comprising crossing the maize plant of claim 45 with either a second plant of another maize line, or a non-transformed maize plant of the line NP2171, so that the genetic material of

the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element.

47. (New) A method for developing a maize plant in a maize plant breeding program using plant breeding techniques, which include employing a maize plant, or its parts, as a source of plant breeding material, comprising: obtaining the maize plant, or its parts, of claim 2 as a source of said breeding material.

48. (New) A maize plant breeding program of claim 47, wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

49. (New) A maize plant, or parts thereof, produced by the method of claim 47.